DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Incorporated
Ms. Anna Hwang
Regulatory Associate
3203 Kashiwa Street
Torrance, California 90505

June 3, 2015

Re: K143204
Trade/Device Name: AOS Clavicle Intramedullary Device
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDW
Dated: April 27, 2015
Received: April 29, 2015

Dear Ms. Hwang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143204

Device Name
AOS Clavicle Intramedullary Device

Indications for Use *(Describe)*
The AOS Clavicle Intramedullary Device is intended to be used to repair an acute fracture, mal-union, or non-union of the Clavicle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ADVANCED ORTHOPAEDIC SOLUTIONS

5. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: May 19, 2015

SUBMITTED BY:
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Phone: (310) 533-9966

CONTACT PERSON:
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Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS Clavicle Intramedullary Device

COMMON NAME: Clavicle Nail

CLASSIFICATION: Class II, 21 CFR 21 CFR 888.3020, Intramedullary fixation rod
888.3040, Smooth or Threaded Metallic Bone Fixation Fastener

DEVICE CODE: HSB and JDW

SUBSTANTIALLY EQUIVALENT DEVICES:
Primary Predicate: DePuy Orthopaedics Rockwood Clavicle Pin (510(k): K103001, Cleared February 17, 2011);
Reference Device: Sonoma Orthopedic EnsplintCMx Clavicle Pin (510(k): K081832, Cleared October 10, 2008); and
Reference Device: Synthes Elastic Intramedullary Nail (EIN) System: K971783, Cleared July 18, 1997.

DEVICE DESCRIPTION: The system consists of an intramedullary titanium device and a fully threaded 2.7mm cortical screw for Clavicle fracture fixation.

INDICATIONS FOR USE: The AOS Clavicle Intramedullary Device is intended to be used to repair an acute fracture, mal-union, or non-union of the Clavicle.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the AOS Clavicle Intramedullary Device to the predicate devices. The proposed

system has the same indications for use, is similar in shape, design and material, and has the same fundamental technology.

PRECLINICAL TESTING: The AOS Clavicle Intramedullary Device was subjected to comparative mechanical testing per a four point bend test based on ASTM F1264-03. The results demonstrate that the AOS Clavicle Intramedullary Device and accessories are substantially equivalent to the predicate.